



ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2021-0787; FRL-10504-01-OCSP]

Fluridone; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of fluridone in or on multiple commodities which are identified and discussed later in this document. SePRO Corporation requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Objections and requests for hearings must be received on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2021-0787, is available at <https://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room and the OPP Docket is (202) 566-1744. For the latest status information on EPA/DC services and docket access, visit <https://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Daniel Rosenblatt, Registration Division (7505T), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (202) 566-2875; email

address: *RDFRNotices@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Office of the *Federal Register's* e-CFR site at <https://www.ecfr.gov/current/title-40>.

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a(g), any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2021-0787 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing and must be received by the Hearing Clerk on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Addresses for mail and hand delivery of objections and hearing requests

are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2021-0787, by one of the following methods:

- *Federal eRulemaking Portal*: <https://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

- *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <https://www.epa.gov/dockets/where-send-comments-epa-dockets>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <https://www.epa.gov/dockets>.

II. Summary of Petitioned-For Tolerances

In the *Federal Registers* of March 22, 2022 (87 FR 16133) (FRL-9410-11) and June 22, 2022 (87 FR 37287) (FRL-9410-02), EPA issued documents pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of pesticide petitions (PP 1F8940 and PP 2F8996, respectively) by SePRO Corporation, 11550 N. Meridian Street, Suite 600, Carmel, IN 46032. The petitions requested that 40 CFR part 180.420 be amended by establishing tolerances for residues of the herbicide fluridone in or on the raw agricultural commodities of Berry and small fruit, group 13-07; Fruit, citrus, group 10-10; Fruit, pome, group 11-10; Tropical and subtropical, small fruit, edible peel subgroup 23A; Tropical and subtropical, medium and large

fruit, smooth, inedible peel, subgroup 24B; Hop, dried cones; Nut, tree, group 14-12; and Rice, grain at 0.1 parts per million (ppm) (PP 1F8940); Animal feed, nongrass, group 18 and Grass, forage, fodder and hay, group 17 at 0.15 ppm (PP 1F8940); and Peanut at 0.1 ppm and Peanut, hay at 0.15 ppm (PP 2F8996). The petitions also requested to remove the existing tolerances for indirect or inadvertent residues of the herbicide fluridone, including its metabolites and degradates, from 40 CFR 180.420(d) in or on Berry, group 13; Fruit, citrus, group 10; Fruit, pome, group 11; Hop, dried cones; Nut, tree, group 14 at 0.1 ppm; Animal feed, nongrass, group 18 and Grass, forage at 0.15 ppm (PP 1F8940); and the existing time-limited tolerances for residues of the herbicide fluridone, including its metabolites and degradates, from 40 CFR 180.420(b) in or on Peanut and Peanut, hay at 0.1 ppm (PP 2F8996). Those documents referenced summaries of the petitions prepared by SePRO Corporation, which are available in the docket, <https://www.regulations.gov>. Comments were received in response to the March 22, 2022, Notice of Filing (PP 1F8940). EPA's response to these comments is discussed in Unit IV.C.

Based upon review of the data supporting the petition and in accordance with its authority under FFDCA section 408(d)(4)(A)(i), EPA is removing the following individual commodities from 40 CFR 180.420(a)(2), because the new crop group/subgroup tolerances established in this action will cover these commodities: pistachio (in crop group 14-12), tangerine (in crop group 10-10), pomegranate (in crop subgroup 24B), and avocado (in crop group 24B). Additionally, based on standard commodity definitions, EPA is updating the petitioned-for commodity definition "Tropical and subtropical, medium and large fruit, smooth, inedible peel, subgroup 24B" to "Tropical and subtropical, medium to large fruit, smooth, inedible peel, subgroup 24B."

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(b)(2)(A)(ii) of FFDCA defines "safe" to mean that "there is a reasonable certainty

that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....”

Consistent with FFDCA section 408(b)(2)(D), and the factors specified therein, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for fluridone, including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with fluridone follows.

In an effort to streamline its publications in the *Federal Register*, EPA is not reprinting sections of the rule that would repeat what has been previously published in tolerance rulemakings for the same pesticide chemical. Where scientific information concerning a particular chemical remains unchanged, the content of those sections would not vary between tolerance rulemakings, and EPA considers referral back to those sections as sufficient to provide an explanation of the information EPA considered in making its safety determination for the new rulemaking.

EPA has previously published tolerance rulemakings in 2016, 2020, and 2022 for fluridone in which EPA concluded, based on the available information, that there is a reasonable certainty that no harm would result from aggregate exposure to fluridone and established tolerances for residues of that chemical. EPA is incorporating previously published sections from these rulemakings as described further in this rule, as they remain unchanged.

Toxicological profile. For a discussion of the toxicological profile for fluridone, see Unit III.A. of the May 18, 2020, final rule (85 FR 29633) (FRL-10007-09).

Toxicological points of departure/Levels of concern. For a summary of the toxicological points of departure and levels of concern for fluridone used for the human health risk assessment, see Unit III.B. of the February 17, 2016, final rule (81 FR 7982) (FRL-9941-69).

Exposure assessment. EPA's dietary exposure assessments have been updated to include the additional exposure from the petitioned-for tolerances for fluridone. Acute and chronic unrefined dietary exposure assessments were performed for fluridone that incorporated tolerance-level residues, 100% crop treated (PCT) assumptions, default processing factors, and empirical processing factors where available. These assessments were revised to reflect the updated Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID), Version 4.02, which incorporates 2005-2010 consumption data from the United States Department of Agriculture (USDA) National Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEIA). The acute and chronic estimated drinking water concentrations (EDWCs) of 150 parts per billion (ppb) and 107 ppb, respectively, are unchanged from the May 18, 2020, final rule and were directly incorporated into the dietary assessments. A cancer dietary assessment was not conducted as fluridone is classified as "not likely" to be a human carcinogen. The residential exposure assessment also has not changed since the May 18, 2020, final rule because there are no proposed new residential uses. For a summary of the dietary exposure from drinking water and non-dietary exposure, see Unit III.C. of the May 18, 2020, final rule.

Cumulative exposure. Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity." Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not found fluridone to share a common mechanism of toxicity with any other substances, and fluridone does not appear to produce a toxic metabolite produced by other substances. For the purposes of

this tolerance action, therefore, EPA has assumed that fluridone does not have a common mechanism of toxicity with other substances.

Safety factor for infants and children. EPA continues to conclude that there are reliable data to support the reduction of the Food Quality Protection Act (FQPA) safety factor from 10X to 1X. See Unit III.D. of the May 18, 2020, final rule for a discussion of the Agency's rationale for that determination.

Aggregate risks and determination of safety. EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute population-adjusted dose (aPAD) and chronic population-adjusted dose (cPAD). Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate points of departure (POD) to ensure that an adequate margin of exposure (MOE) exists. For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure.

Acute dietary risks are below the Agency's level of concern: 2.5% of the aPAD for all infants (<1 year old), the population group receiving the greatest exposure. Chronic dietary risks are below the Agency's level of concern: 7.6% of the cPAD for all infants (<1 year old), the population group receiving the greatest exposure. The combined short-term food, water, and residential exposures result in aggregate MOEs of 1,300 for adults and 1,800 for children. The Agency's level of concern for fluridone is an MOE of 100 or below, and these MOEs are therefore not of concern. Because there is no intermediate-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess intermediate-term risk), no further assessment of intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating intermediate-term risk for fluridone. Finally, EPA has concluded that fluridone is not expected to pose a cancer risk, given the lack of evidence of carcinogenicity in the database.

Therefore, based on the risk assessments and information described above, EPA

concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children, from aggregate exposure to fluridone residues. Detailed information on this action can be found in the document titled “Fluridone. Human Health Risk Assessment for the Section 3 Registration Action on Pome Fruit (Crop Group 11-10); Berry and Small Fruit (Crop Group 13-07); Grass Forage (Crop Group 17); Non-grass Animal Feed (Crop Group 18); Tropical and Subtropical, Small Fruit, Edible Peel (Crop Subgroup 23A); Rice; Peanut; Hops; and Crop Group Conversions/Expansions.” in docket ID EPA-HQ-OPP-2021-0787.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methods are available in the Pesticide Analytical Manual (PAM) Volume II to enforce the tolerance expression in plant and animal commodities. A Quick, Easy, Cheap, Effective, Rugged, and Safe (QuEChERS) multiresidue method (Method No. A0013-02) is also available for determining residues of fluridone in various crop commodities, except acidic commodities. This QuEChERS method is considered marginally adequate for determining residues in acidic commodities. These methods may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; email address: *residuemethods@epa.gov*.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCa section 408(b)(4). Codex has not established MRLs for fluridone.

C. Response to Comments

Two comments were received in response to the Notice of Filing published in the *Federal Register* of March 22, 2022 (87 FR 16133) (FRL-9410-11). Neither comment was accompanied

by any substantiation nor data supporting a conclusion that the tolerances being established in this action do not meet the FFDCA safety standard. Although EPA recognizes that some individuals would oppose any use of pesticides on food, section 408 of the FFDCA authorizes EPA to set tolerances for residues of pesticide chemicals in or on food when it determines that the tolerance meets the safety standard imposed by that statute. Upon review of the available information, EPA concludes that these tolerances would be safe.

V. Conclusion

Therefore, tolerances are established for residues of fluridone under 40 CFR 180.420(a)(2) in or on the following raw agricultural commodities: Animal feed, nongrass, group 18 at 0.15 ppm; Berry and small fruit, group 13-07 at 0.1 ppm; Fruit, citrus, group 10-10 at 0.1 ppm; Fruit, pome, group 11-10 at 0.1 ppm; Grass, forage, fodder and hay, group 17 at 0.15 ppm; Hop, dried cones at 0.1 ppm; Nut, tree, group 14-12 at 0.1 ppm; Peanut at 0.1 ppm; Peanut, hay at 0.15 ppm; Rice, grain at 0.1 ppm; Tropical and subtropical, small fruit, edible peel subgroup 23A at 0.1 ppm; and Tropical and subtropical, medium to large fruit, smooth, inedible peel subgroup 24B at 0.1 ppm.

In addition, EPA is removing the established tolerances for indirect or inadvertent residues of fluridone under 40 CFR 180.420(d) in or on the following commodities: Animal feed, nongrass, group 18 at 0.15 ppm; Berry, group 13 at 0.1 ppm; Fruit, citrus, group 10 at 0.1 ppm; Fruit, pome, group 11 at 0.1 ppm; Grass, forage at 0.15 ppm; Hop, dried cones at 0.1 ppm; and Nut, tree, group 14 at 0.1 ppm. Additionally, EPA is removing the established Section 18 emergency exemption tolerances under 40 CFR 180.420(b) in or on Peanut and Peanut, hay at 0.1 ppm. Finally, EPA is removing the established tolerances from 40 CFR 180.420(a)(2) in or on the following individual raw agricultural commodities as they are redundant with the established crop group/subgroup tolerances being established in this rulemaking: Avocado, Pistachio, Pomegranate, and Tangerine at 0.1 ppm.

VI. Statutory and Executive Order Reviews

This action establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001), or to Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerances in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or Tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or Tribal Governments, on the relationship between the National Government and the States or Tribal Governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian Tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this action. In

addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the *Federal Register*. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: January 13, 2023.

Daniel Rosenblatt,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, for the reasons stated in the preamble, EPA is amending 40 CFR chapter I as follows:

PART 180—TOLERANCES AND EXEMPTIONS FOR PESTICIDE CHEMICAL RESIDUES IN FOOD

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

2. In § 180.420:

a. In paragraph (a)(2) amend the table by:

- i. Removing the entry for “Avocado”;
- ii. Adding in alphabetical order the entries “Animal feed, nongrass, group 18”; “Berry and small fruit, group 13-07”; “Fruit, citrus, group 10-10”; “Fruit, pome, group 11-10”; “Grass, forage, fodder and hay, group 17”; “Hop, dried cones”; “Nut, tree, group 14-12”; “Peanut”; “Peanut, hay “;
- iii. Removing the entries for “Pistachio” and “Pomegranate”;
- iv. Adding in alphabetical order the entry “Rice, grain”;
- v. Removing the entry for “Tangerine”;
- vi. Adding in alphabetical order the entries “Tropical and subtropical, small fruit, edible peel, subgroup 23A”; and “Tropical and subtropical, medium to large fruit, smooth, inedible peel, subgroup 24B”.

b. Removing and reserving paragraph (b).

c. In paragraph (d), amend the table by removing the entries for “Animal feed, nongrass, group 18”; “Berry, group 13”; “Fruit, citrus, group 10”; “Fruit, pome, group 11”; “Grass, forage”; “Hop, dried cones”; and “Nut, tree, group 14”

The additions read as follows:

§ 180.420 Fluridone; tolerances for residues.

(a) * * *

(2) * * *

Commodity	Parts per million
Animal feed, nongrass, group 18	0.15
Berry and small fruit, group 13-07	0.1
* * * * *	
Fruit, citrus, group 10-10	0.1
Fruit, pome, group 11-10	0.1
* * * * *	
Grass, forage, fodder and hay, group 17	0.15
* * * * *	
Hop, dried cones	0.1
* * * * *	
Nut, tree, group 14-12	0.1
Peanut	0.1
Peanut, hay	0.15
* * * * *	
Rice, grain	0.1
* * * * *	
Tropical and subtropical, small fruit, edible peel, subgroup 23A	0.1
Tropical and subtropical, medium to large fruit, smooth, inedible peel, subgroup 24B	0.1

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[FR Doc. 2023-00949 Filed: 1/19/2023 8:45 am; Publication Date: 1/20/2023]